Imprimis Pharmaceuticals to Make a Lower Cost Compounded and Customizable Alternative to Thiola®

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p>SAN DIEGO, Feb. 10, 2016 /PRNewswire/ -- Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY), a specialty pharmaceutical company focused on the development and commercialization of proprietary compounded drug therapies, today announced plans to introduce new patent-pending tiopronin and potassium citrate delayed release (DR) compounded formulations that may be prescribed by physicians as a lower cost therapeutic alternative to FDA-approved Thiola. The formulations are expected to be available to prescribers in April 2016. Thiola, made of tiopronin as its active drug ingredient, is commonly prescribed for the prevention of cystine kidney stone formation in patients who do not respond to dietary changes and increased fluids. According to the National Organization for Rare Disorders, in addition to chelating medications such as tiopronin, potassium citrate is often co-prescribed and taken separately to make the urine more alkaline, potentially reducing cystine crystallization and stone formation.

Imprimis believes that its patent-pending compounded combination of tiopronin and potassium citrate may improve patient compliance. Additionally, FDA-approved Thiola is only available as a 100 mg tablet and many cystinuria patients take 10 or more tablets per day. The company's formulation is customizable, allowing physicians to choose a more precise dosage based on the needs of their patients. Customization of this medication could potentially reduce the number of capsules taken daily for this chronic condition.

Cystinuria is an inherited disease that causes stones made of the amino acid cystine to form in the kidneys, bladder and/or urethra. There are an estimated 10,000 to 12,000 patients in the U.S. who suffer from this chronic condition and 4,000 to 5,000 of them may be candidates for Thiola. In 2014, Retrophin LLC and its CEO at the time, Martin Shkreli, acquired the licensing rights of Thiola from Mission Pharmacal Company and increased the price of Thiola 2,000% from $1.50 per tablet to $30 per tablet, resulting in some cystinuria patients having to grapple with costs of this therapy exceeding more than an estimated $100,000 per year. Since Mr. Shkreli's departure from Retrophin, the high price of Thiola remains intact. Imprimis' compounded alternative containing tiopronin, the active drug ingredient in Thiola, and potassium citrate, may reduce the cost of therapy for cystinuria patients by more than 70%.

"Due to the recent increase in the price of Thiola, many cystinuria patients have been switched to an alternative treatment such as captopril, which is FDA-approved for hypertension and heart failure. The off-label use of captopril in cystinuria patients without hypertension increases the risk of excessive blood pressure lowering, dizziness and fatigue. The availability of Imprimis' new customizable compounded drug will provide patients with access to an affordable choice containing both the active ingredient tiopronin and potassium citrate, which are often taken separately with tiopronin," stated Dr. Christian Mende, a nephrologist and clinical professor at University of California at San Diego.

Mark L. Baum, CEO of Imprimis stated, "After we made alternative compounded formulations available for physicians and patients who were dealing with the 5,000% Daraprim® price hike, another old off-patent branded drug that had no generic competition, we were contacted by thousands of patients requesting help with over 100 FDA-approved drugs that also experienced massive and nearly overnight price hikes. We heard the horror stories of patients with access problems directly connected to pricing issues. Cystinuria patients in need of Retrophin's Thiola were among the most frequent requests we received because in many cases, they were being switched to non-tiopronin based drugs. As in the Daraprim case, we are planning to offer lower cost customizable compounded therapeutic alternatives for physicians and patients. We expect to continue to address the needs of patients with additional new formulations during 2016."

Mr. Baum concluded, "Our *Imprimis Cares* program is focused on patient access. To the average American who needs an FDA-approved drug they cannot afford because of the legal and predatory pricing policies of some pharmaceutical companies, or

because they have an unaffordable co-pay or a $6,000 annual drug benefit deductible, the drug they need is in effect commercially unavailable – for economic reasons. Last week, the FDA's Director of the Center for Drug Evaluation and Research, discussed during her testimony at the House Oversight and Government Reform Committee, that approximately 12% of branded drugs have not and may not face generic competition. This competition vacuum creates artificial legal monopolies for some companies, which has led to the massive price hikes we have seen over the past few years. We are responding to the needs of real people with real and immediate problems by offering therapeutically relevant low cost solutions compared to some high priced FDA-approved drugs that simply do not, and according to the FDA, likely will not have any competition. We believe our plan to help decrease drug costs for patients and payors is consistent with our mission, vision and values and will in turn increase long term value for our shareholders."

Imprimis is reviewing partnership opportunities to clinically develop proprietary formulations in its *Imprimis Cares* program. Interested insurance companies, pharmacy benefit managers (PBMs), physicians, patients, and other interested parties may request information regarding the new tiopronin and potassium citrate DR compounded formulations and other *Imprimis Cares* compounded formulations at http://imprimisCares.com/contact/ or contact Gary Seelhorst, Vice President of Business Development at gseelhorst@imprimispharma.com.

About the *Imprimis Cares*™Program
The *Imprimis Cares* program and its team of compounding pharmacists will work with physicians and their patients to ensure they have affordable access to the medicines they need by compounding customizable therapeutic alternatives using the over 7,800 FDA-approved drugs as components. The *Imprimis Cares* program, available in all 50 states, will work with all third party insurers, pharmacy benefit managers and buying groups to offer its patient specific customizable compounded drug formulations at prices that ensure accessibility. Imprimis is committed to providing high quality medications compounded at FDA-inspected and PCAB-accredited facilities. All active drug ingredients used as components are FDA-approved and manufactured to the USP Monograph or a similarly accepted standard. We strive to meet and/or exceed all quality standards for the formulations we dispense and we are committed to transparency to our customers when it comes to the batch and lot testing we do, including providing sterility test results for each order we dispense for a sterile compounded drug and potency testing results for non-sterile compounded drugs. For more information, visit www.ImprimisCares.com.

ABOUT IMPRIMIS PHARMACEUTICALS
San Diego-based Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY) is a national leader in the development, production and dispensing of novel compounded pharmaceuticals. The company's business primarily consists of four therapeutic segments including ophthalmology, urology, sinus and integrative medicine. Imprimis dispenses compounded pharmaceuticals in all 50 states from four facilities located in California, Texas, New Jersey and Pennsylvania. For more information about Imprimis, please visit the corporate website at www.ImprimisPharma.com.

Imprimis compounded formulations are not FDA approved and may only be prescribed pursuant to a physician prescription for an individually identified patient consistent with federal and state laws governing compounded drug formulations.

Thiola® is a registered trademark of Mission Pharmacal Company. Imprimis is not affiliated with Mission Pharmacal Company nor Thiola®. Thiola® is an FDA-approved drug. Please consult with your physician regarding which prescription options are most suitable for your specific needs.

Daraprim® is a registered trademark of Turing Pharmaceuticals LLC. Imprimis is not affiliated with Turing Pharmaceuticals LLC nor Daraprim®. Daraprim® is an FDA-approved drug. Please consult with your physician regarding which prescription options are most suitable for your specific needs.

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